REMARKS

In the Office Action of February 18, 2004, The Examiner rejected claims 1 to 21 as being anticipated both by Bierman '523, and by Konopka '173.

Section 102 Rejections:

(a) The Presently Claimed Invention:

Claim 1, as amended, sets forth a device, comprising:

(1) a **housing** which has a bottom and is placed against the patient's skin
(e.g.: #202 in Fig. 2),
(2) an **infusion cannula** that extends away from the housing;
(e.g.: #204 in Fig. 2);
(3) a **connecting hub** which is attachable to the housing, (e.g.: #206 in Figs. 1 and 2), wherein the connecting hub **has an internal Y-shaped flow channel structure**. (e.g.: as seen in Figs. 2 and 10); and
(4) theY-shaped flow channel structure has at least two ports, one of said ports being a first flow channel adapted to be connected to the cannula and a second of said ports being a second flow channel adapted to be connected to the cannula.

An advantage of the present Y-shaped flow structure with at least two ports in hub 206 is that it permits a user to simultaneously deliver a multiple infusates such as one at basal rate of delivery from one device (e.g.: through an insulin infusion line 208 into connecting hub 206) and also a bolus injection through another device (e.g.: through a syringe inserted through a septum 500 in the connecting hub 206, see Fig. 1).

Thus, two different medication streams may be simultaneously delivered into a patient through a single infusion needle 204. (as shown in Fig. 2).

This has an important practical benefit, for example in insulin infusion, where a patent may be receiving a basal (low) continuous rate infusion, but because of physical activity or food intake changes needs a rapid infusion at a high rate, but for a short duration. In the past it was necessary for the patient to suffer a needle stick and the patient might be inclined to skip the bolus infusion to avoid the pain. Further, every needle stick involves risk of infection.

The present invention avoids the needle stick as the second port provides a pathway through the existing cannula.

Similarly, claim 17 also sets forth:

an infusion cannula (204) supported by a flat bottomed housing (202), and a connecting hub (206) having an internal Y-shaped flow structure.

(b) The Bierman and Konopka Systems:

Bierman is a system for ***anchoring*** a Y-shaped catheter against a patient's skin. The Bierman system works to prevent a *catheter* from moving around such that fluid flow through the various branches of the catheter does not become blocked (i.e.: by bending of the catheter branches). It has no disclosure of any means to infuse anything into the body.

Konopka shows a standard infusion device which is placed into a patient's skin to deliver medication through a single infusion line (#18, Fig. 1) into the patient.

(c) Bierman and Konopka Distinguished:

(i) Bierman:

Under sec. 102, a proper anticipation rejection requires every element of the claimed invention to be present in the cited reference. Under sec 103 (should the examiner decide to reapply the references under this section), requires that the invention be render obvious by the teaching of the reference. If several references are combined, it is not sufficient that a person **could** combine teachings.

Claim 1 recites an infusion **cannula** (#204 in Fig. 2) extending downwardly away from the housing (#202 in Fig. 2) and theY-shaped flow channel structure having at least two ports, one of said ports being a first flow channel adapted to be connected to the cannula and a second of said ports being a second flow channel adapted to be connected to the cannula.

Similarly, claim 17 defines a method of similar scope.

Beirman, on the other hand, is completely lacking in any teaching of infusion. In contrast, Bierman simply provides a lock to hold a Y-shaped **catheter** from moving around on the surface of a patient. A "catheter" is not the same as a "cannula", as follows and provides no teaching of infusion.

As commonly understood, a **catheter** is a long flexible tube for delivering fluid to (or from) a patient. In contrast, a **cannula** is more akin to a sharp piercing needle or stiff tube that pierces through the patient's skin.

As such, Bierman does not disclose any form of **infusion cannula** at all nor the Y shaped channel and ports, as claimed.

Consequently, withdrawal of the present anticipation and potential obviousness (sec 103) rejections in view of Bierman is respectfully requested.

(ii) Konopka:

The Examiner contends that Konopka discloses a Y-shaped flow channel.

The Applicants respectfully disagree, as follows. It is agreed that a Y-shaped channel can be have orthogonal intersections, as in Konopka, but that is not sufficient to render the amended claims unpatentable (under sec 102 or sec 103).

Referring to Figs. 1 and 2 of Konopka, a medication delivery tube 18 extends from hub 48. A luer connector 20 is provided at one end of medication delivery tube 18. In use, luer connector 20 is attached to a medication fluid source or pump (not shown). Medication then passes through tube 18 into hub 48, and then out through soft cannula 14 into the patient.

An operator uses handle 26 / end cap 30 to initially place soft cannula 14 into the patient. Specifically, the operator pushes down on handle 26 / end cap 30 to place insertion needle 22 and soft cannula 14 into the patient. (As shown in Fig. 2). Then, the operator pulls up on handle 26 / end cap 30 to remove needle 22 from the patient. (As shown in Fig. 4). As can be seen, there is only one flow path – i.e.: medication flows through delivery tube 18 and then into the patient through soft cannula 14.

The Applicants note the existence of hole 60 in needle 22 (See Fig. 2). A cross sectional view of this hole is seen in Fig. 3B (which also shows hollow bore 62 in needle 22). An advantage of this hollow needle design is that medication infusion can be carried out even prior to the removal of needle 22 (and its attached handle 26). Specifically, medication fluid

from tube 18 is able to enter fluid chamber 50, and then pass through hole 60, into the hollow bore 62 of needle 22, and then out into the patient.

It is important to note, however, that there is **no fluid path up through needle 22 within handle 26**. As stated at Col. 6, lines 51 to 58:

"...needle **bore 62..... would terminate within the fluid chamber 50** .... [to] provide fluid communication between the fluid chamber 50 and the needle tip 24.

Thus, hollow needle bore 62 only runs from fluid chamber 50 to needle tip 24. There can be no needle bore (i.e.: flow path) upwardly through needle 22 in the region of handle 26. This must be so. If there were an upward flow path through needle 22 (i.e.: within handle 26), blood from the patient would simply squirt out through end cap 30 when the device is initially placed into the patient. Moreover, medication delivered from tube 18 would also simply squirt out through end cap 30 when the device is initially placed into the patient. Holes 60 therefore is not the same as the second flow path of the present claimed invention.

As can be seen, Konopka simply provides a single flow path system. IE: medication from delivery tube 18 passes into the patient through soft cannula 14 (and optionally through needle tip 24 as well).

Clearly the use of Konopka as the basis for a sec 102 rejection must fail, but also as a sec 103 rejection, even if taken in combination with Bierman or other art.

First, Beirman really adds nothing to the combination for the reasons stated above. Second, Konopka itself teaches ***away*** from the claimed invention because, although it might have been possible for Konopka to design the present invention, he clearly choose not to...or was *unable to see* the inventive concept of the present invention. Konopka does not

recognize the fundamental advantages of a multiport infusion site per the present claims. Thus it is impossible to conclude that person skilled in the art could use the teachings of Konopka + Bierman to reach the claimed invention...without the addition of further inventive genius. Consequently, withdrawal of the present anticipation rejections in view of Konopka is respectfully requested.

Of course, if claims 1 and 17 are found allowable, the remaining dependent claims would also be allowable, but it is submitted that these claims stand patentable on their own merit. For example, claims 2-16 provide many additional refinements which are not show or alluded to in the prior art. Indeed the cited art is devoid of helpful suggestions to achieve the claimed combinations.

The same is true of the dependent method claims 18-21 which clear derive no benefit from Konopka or Bierman as the objective of multiport infusion is never discussed.

Conclusion:

For the reasons presented above, all claims are believed to be in condition for allowance. A Notice of Allowance is therefore respectfully requested.

Should the Examiner feel that a telephone conference would advance prosecution of the present application, he is invited to call the undersigned attorney at the number listed below.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
David R. Heckadon
Registration No. 50,184

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: July 6, 2004.

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